application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1". The Examiner has alleged that there are four groups of inventions as follows: Group I, claims 1-21, 40 and 65, drawn to a method of making microparticles; Group II, claims 22-28 and 66, drawn to a method of spherifying a conjugate; Group III, claims 29-37 and 67, drawn to a method of spherifying a conjugate; and Group IV, claims 41-64, drawn to a biodegradable polymer.

Applicants provisionally elect to prosecute the Group I claims, claims 1-21, 40 and 65, with traverse.

The Examiner has also alleged that the claims are directed to more than one species of the generic invention because the species are not so linked as to form a single general inventive concept under PCT Rule 13.1. The Examiner notes that the species are the peptides that are listed at page 3 of the instant Office Action. Applicants provisionally elect somatostatin, with traverse. It is evident that claims 1-21, 40 and 65 read upon somatostatin as somatostatin is described, in the specification at pages 5 and 6, as a "drug" as that term is used in claim 1.

Applicants traverse the restriction requirement and the Examiner's characterization that the species are not related to one another. Applicants point out to the Examiner the apparent inconsistency of the Examiner's interpretation of unity of invention under the standard of a single inventive concept as

recited in PCT Rule 13.1 versus the PCT International Search Authority's and PCT International Preliminary Examining Authority's (IPEA) interpretation of the very same rule. The IPEA did not find that there was more than a single inventive concept claimed in Applicants' application and issued both a Search Report and an International Examination Report based on all of the claims presented to the PCT.

Despite that unity of invention of the claims was found to be satisfied by the PCT authorities, the Examiner alleges that the claims lack a same or corresponding technical feature among the claims. As an initial note, Applicants point out that the methods do not have to share the "same mode of operation steps" as the Examiner requires at page 2 of the instant Office Action. Sharing an inventive concept, i.e., satisfying the requirement of unity of invention, (Rule 13.1 PCT), does not require having the same steps. Rather the rules only require that a "special technical feature" be present in the claims, (Rule 13.2 PCT), not that the method claims have to have identical number of steps that perfectly correspond with each other.

The technical feature which is common to Group I claims (1-21, 40, 65), Group II claims (22-28, 66) and Group III claims (29-37, 67) is that they are all methods for making microparticles of a polymer and a drug. More specifically, they all define a method for making microparticles of a particular type of polymer, (a free carboxyl group-containing biodegradable

polymer), and a particular type of drug, (a free amino group-containing drug), wherein the polymer and the drug have a particular type of relationship with each other (they are ionically bound to each other).

Further, the technical feature which is shared between the Group IV claims (41-64) and claims 1-40 and 65-67 is that the free carboxyl-containing biodegradable polymers of claims 41-64 comprise a subgenus of the free carboxyl-containing biodegradable polymers of claims 1-40 and 65-67. (The free carboxyl group is provided in claim 41 by the inclusion of tartaric acid.) In this regard Applicants note that it appears from the Examiner's statement at numbered paragraph 2, page 2, of the Instant Office Action that the Examiner has misunderstood the role of the biodegradable polymer of claims 41-64. In particular, the Examiner states that "the invention of Group IV is not required to be made by any of the methods of Groups I, II, or III." Applicants respectfully remind the Examiner that the biodegradable polymer of claims 41-64 would be *used by*, not *produced by*, the method of claims 1-40 and 65-67. Applicants respectfully further remind the Examiner that the unity of invention rules do not require that the biodegradable polymer of claims 41-64 be suitable for use only in the method of claims 1-40 and 65-67.

With regard to the election of species, the essential feature of the drug is that the drug possess an ionogenic amine

that is capable of binding to a polymer. This is the special technical feature which is common to all of the species and is the general inventive concept which the Examiner seeks.

Based upon the foregoing, the restriction requirement should be withdrawn and all of claims 1-37 and 40-67 should be prosecuted together. Prompt and favorable action is earnestly solicited.

Respectfully submitted,

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Brian R. Morrill
Attorney for Applicants
Reg. No. 42,908

Biomeasure Inc.
27 Maple Street
Milford, MA 01757-3650
(508) 478-0144